

## CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Rivopharm SA, Centro Insema, 6928 Manno**, Authorisation No. 511351-102608771 with its site **Rivopharm SA, Centro Insema, 6928 Manno, Switzerland**, Site No. 1000456 has been duly authorised to perform the manufacturing activities according to the table below;

that the company is keeping the required level for Good Manufacturing Practices for Medicinal Products (GMP) according to the Swiss regulations in force. These regulations are in accordance with the requirements for good practices in the manufacture and quality control of the Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S) as well as with The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union/Canada and Switzerland;

that the manufacturing plant of the company is subject to official periodic inspections; the last regular inspection was conducted on **12.05.2021** (dd.mm.yyyy). Distant assessment

No.	Operation	Scope*
<b>1</b>	<b>MANUFACTURE OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)</b>	
<b>1.2</b>	<b>Non-sterile products</b>	
1.2.1	Non-sterile products (processing operations for the following dosage forms)	
1.2.1.1	Capsules, hard shell	H/V, I
1.2.1.13	Tablets	H/V, I
1.2.2	Batch certification (technical release)	H/V, I
<b>1.5</b>	<b>Packaging</b>	
1.5.1	Primary packaging	
1.5.1.1	Capsules, hard shell	H/V, I
1.5.1.13	Tablets	H/V, I
1.5.2	Secondary packaging	H/V
<b>1.6</b>	<b>Quality control testing</b>	
1.6.2	Microbiological: non-sterility	H/V, I
1.6.3	Chemical/Physical	H/V, I

\* Scope of authorisation:

- H/V Human and veterinary medicinal products, without investigational products
- V Veterinary medicinal products only, without investigational products
- I Human investigational medicinal products
- Not specified

Berne, **22.06.2021** (dd.mm.yyyy)  
**No. GMP-CH-1002273**

Swissmedic, Swiss Agency for  
Therapeutic Products



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